IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9038

Bartle, J. April 2, 2013

Kathleen S. Brandt ("Ms. Brandt" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. John H. Brandt, Ms. Brandt's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In December, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Michael N. Rubinstein, M.D., F.A.C.C. Dr. Rubinstein is no stranger to this litigation. According to the Trust, he has signed at least 213 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated September 4, 2002, Dr. Rubinstein attested in Part II of claimant's Green Form that Ms. Brandt suffered from moderate mitral regurgitation and an

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3. (...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

abnormal left atrial dimension.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $597,201.[5]

In the report of claimant's echocardiogram, Dr. Rubinstein stated that claimant had "[m]oderate mitral valve regurgitation." Dr. Rubinstein, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In May, 2006, the Trust forwarded the claim for review by Zuyue Wang, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Wang determined that there was no reasonable medical basis for Dr. Rubinstein's representation that Ms. Brandt had moderate mitral regurgitation because the echocardiogram demonstrated only mild mitral regurgitation. Dr. Wang explained,

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4. Dr. Rubinstein also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Trust disputes that claimant had an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, we need not resolve this issue given our determination with respect to claimant's level of mitral regurgitation.

"The RJA/LAA ratio is 14%. The RJA encircled should not include the areas of low velocity flow."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, Ms. Brandt argued that there was a reasonable medical basis for Dr. Rubinstein's representation of moderate mitral regurgitation. To that end, claimant submitted videotaped statements under oath of Dr. Rubinstein, Duncan Salmon, M.D., F.A.C.C., and Mark M. Applefeld, M.D., wherein each cardiologist explained how he concluded that claimant had moderate mitral regurgitation.[7] In addition, claimant submitted Part II of Green Forms completed by Dr. Rubinstein, Dr. Salmon, and Dr. Applefeld, which were based on claimant's September 4, 2002 echocardiogram. Each cardiologist concluded that claimant had moderate mitral regurgitation. Moreover, claimant submitted a number of still-frame images taken from her September 4, 2002

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Brandt's claim.

7. Dr. Salmon and Dr. Applefeld also are not strangers to this litigation. According to the Trust, they have appeared as experts for claimants in at least 29 and 24 contests, respectively.

echocardiogram, which, according to claimant, showed "systolic, apical mitral regurgitation of a moderate degree."

Claimant also argues that this court in PTO No. 2640 (Nov. 14, 2002) and Harvey Feigenbaum, M.D. in the fifth edition of Echocardiography explained that a cardiologist should use the "maximum or largest regurgitant jet ... when quantifying the degree of mitral regurgitation." Claimant further suggests that a cardiologist should include in his or her measurement "'the entire mitral regurgitant jet, including the surrounding lower flow spray.'" In addition, claimant submits that the regurgitation demonstrated by an echocardiogram performed on a Diet Drug Recipient may vary within the same study because of the typical patient size. Finally, claimant asserts that: (1) her echocardiogram should be viewed more favorably because it was conducted in the normal course of treatment rather than in anticipation of submitting a claim; (2) the proper technique for reviewing echocardiograms is to employ a stop action and slow motion method; (3) the limitations of echocardiography dictate that if moderate mitral regurgitation is present at any point in the study, it is present throughout the study; (4) inter-reader variability may account for the difference of opinion among cardiologists; (5) the auditing cardiologist should not simply substitute his opinion for that of the attesting physician; and (6) three cardiologists reviewed her echocardiogram and found

that she had moderate mitral regurgitation and, therefore, there is a reasonable medical basis for her claim.[8]

The Trust then issued a final post-audit determination again denying Ms. Brandt's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On December 19, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6785 (Dec. 19, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant advised the Special Master that she did not intend to file a response, instead, she intended to rely on the material she submitted in contest. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical

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8. Claimant also argued that, in reviewing her claim, the court should consider that certain claims have passed audit "mistakenly" and that certain auditors have been removed for undisclosed conflicts. We disagree. Claimant does not attempt to explain how these circumstances had any impact on Dr. Wang's review of her specific claim. As we consistently have stated, the relevant inquiry is whether a claimant has established a reasonable medical basis for his or her claim, an inquiry that is to be made on a claim-by-claim basis. See, e.g., PTO No. 6280 at 9 (May 19, 2006).

Advisor[9] to review claims after the Trust and claimant have had their opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded there was no reasonable basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante explained:

> I reviewed the tape of the Claimant's echocardiogram of attestation.... All of the usual echocardiographic views were obtained. However, the study was not performed in accordance with the usual standards of care. There was markedly increased color gain with color artifact noted within the myocardial tissues and even outside of the heart. However, the Nyquist limit was appropriately set at 67.3 cm/second at a depth of 23 cm in the apical views. In addition, the left atrium was measured in a non-qualifying parasternal short-axis rather than parasternal short-axis view.
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> .... Visually, mild to moderate mitral regurgitation was suggested in the apical views with a posterolaterally directed jet into the left atrium. I digitized the cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet could be best evaluated in the mid portion of systole. In spite of excessive color gain, I was able to accurately planimeter the mitral regurgitant jet in the mid portion of systole. In the apical four chamber view, the largest representative RJA in the mid portion of systole was 3.1 cm2. The LAA in the apical four chamber view was 17.4 cm2. Therefore, the largest representative RJA/LAA ratio was 18% in the apical four chamber view. I was also able to accurately planimeter the RJA in the mid portion of systole in the apical two chamber view in spite of increased color gain. In the apical two chamber view, the largest representative RJA was 3.1 cm2 in the mid portion of systole. The LAA in the apical two chamber view was 17.0 cm2. Therefore, the largest representative RJA/LAA ratio in the apical two chamber view was 18%. There

> were no RJA/LAA ratios that reached 20%. Review of the still frames that accompanied the Special Master Record occurred and these were correlated in real time on the [echocardiogram] tape. Most of these still frames demonstrated color artifact rather than true mitral regurgitation. The still frames that did demonstrate mitral regurgitation were those used to determine the RJA in the mid portion of systole. There were no sonographer determined RJA's or LAA's on the tape. There were no tracings of the supposed RJA's or LAA's submitted by the Claimant's cardiologists.
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> [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the echocardiogram of September 4, 2002 demonstrated mild mitral regurgitation with comments as above. The RJA/LAA ratio did not reach 20% when quantitative measurements were performed. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study when taking appropriate measurements even taking into account inter-reader variability.[10]

After reviewing the entire show cause record, we find claimant's arguments are without merit. First, we reject claimant's argument that the still-frame images claimant submitted demonstrate a reasonable medical basis for the attesting physician's finding that Ms. Brandt had moderate mitral

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10. Dr. Vigilante also determined that there was no reasonable medical basis for the attesting physician's determination that claimant had an abnormal left atrial dimension because her left atrium measured 3.8 cm in the antero-posterior dimension and 4.9 cm in the supero-inferior dimension. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See Settlement Agreement § IV.B.2.C.(2)(b).

regurgitation. Dr. Wang reviewed claimant's echocardiogram and concluded that it demonstrated only mild mitral regurgitation. She explained, "The RJA encircled should not include the areas of low velocity flow."[11] Dr. Vigilante also reviewed claimant's echocardiogram and concluded that it demonstrated only mild mitral regurgitation. Specifically, Dr. Vigilante measured claimant's mitral regurgitation and concluded that the largest representative RJA/LAA ratio was 18%.[12]

Although still frames are necessary to determine a claimant's level of mitral regurgitation, they alone are not sufficient. See PTO No. 6897 at 7 (Jan. 26, 2007). Indeed, we have determined that "'[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved.'" Id. (quoting PTO No. 2640 at 9). As stated previously, moderate mitral regurgitation is present where the RJA/LAA in any apical view is equal to or greater than 20%. See Settlement Agreement § I.22. Based on Dr. Wang's and Dr. Vigilante's specific determinations that claimant's RJA/LAA ratio did not come close to 20%, these still-frame images alone do not provide a reasonable medical

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11. Given Dr. Wang's specific finding, we disagree with claimant that the auditing cardiologist simply substituted her opinion for that of the attesting physician.

12. Despite an opportunity to do so, claimant did not submit a substantive response to the Technical Advisor Report. See Audit Rule 34.

basis for Dr. Rubinstein's representation that claimant had moderate mitral regurgitation.

We also disagree with claimant that "lower flow spray" is considered mitral regurgitation. We have consistently held that conduct "beyond the bounds of medical reason" can include characterizing low velocity flow as mitral regurgitation. PTO No. 2640 at 11-13, 15, 22, 26. We have further found that "[o]n a color flow Doppler echocardiogram, mitral regurgitation will thus display as a high velocity, mosaic blue/green teardrop shaped jet that borders the mitral valve leaflets and expands into the left atrium throughout at least a portion of systole." Id. at 10-11 (footnote omitted). There is nothing to indicate that including low velocity flow as mitral regurgitation is permissible under the Settlement Agreement. Significantly, claimant does not contest that her physicians include low velocity flow as mitral regurgitation in determining that she had moderate mitral regurgitation. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.[13]

Finally, to the extent claimant argues that inter-reader variability accounts for the difference in the opinions of the attesting physician and the auditing

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13. For this reason as well, we reject claimant's argument that there is a reasonable medical basis for her claim because the echocardiogram on which the Green Form was based was performed during the course of regular treatment.

cardiologist, such argument is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the opinions of claimant's cardiologists cannot be medically reasonable where the auditing cardiologist and Technical Advisor concluded, and claimant did not adequately dispute, that Ms. Brandt's mitral regurgitation only was mild. To conclude otherwise would allow a claimant with less than moderate mitral regurgitation to receive Level II Matrix Benefits. This result would render meaningless the standards established in the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Brandt's claim for Matrix Benefits and the related derivative claim submitted by her spouse.